Remarks/Arguments

Claims 1-5, 11 and 12 are pending and under consideration.

Claims 6-10 and 12-15 were previously canceled in the Amendment and Response filed on December 12, 2002.

Claims 16 and 17 are new.

Claims 1 and 11 are currently amended. The amendments made to claims 1 and 11 incorporate subject matter of canceled claims 1 and 12, respectively.

No new subject matter has been added.

Thus, after entry of this Amendment, Claims 1, 3-5, 11, 16 and 17, are pending and under consideration.

The various amendments of the claims, as well as the pending rejections, are discussed in detail below in the order raised by the Patent Office.

Amendment of the Claims

Claims 1 and 11 have been amended to recite with greater particularity certain features recited by reference to the specification or other claims.

New Claims 16 and 17 have been added to recite with greater particularity species encompassed by the present invention.

All of the amendments are supported by the original claims and specification, and therefore do not introduce new matter. Indeed, since the amendments merely replace referenced subject matter with the actual text of the referenced matter, the amendments do not alter the scope of the amended claims.

Rejection of Claims 1, 3-5 and 11 under 35 U.S.C. § 112, First Paragraph

Claims 1, 3-5 and 11 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors), at the time the application was filed, had possession of the claimed invention.

Independent claims 1 and 11 have been amended to remove the offending language from the claim and now include the molecular weight range of 50,000 to 200,000 daltons, thereby obviating the basis for this rejection. Claims 4 and 5 are dependent from independent claim 1

and therefore also meet the requirements of 35 U.S.C. § 112, first paragraph in view of the amendments.

Claim 3 has been canceled, thereby obviating the basis for this rejection.

Reconsideration and withdrawal of the pending rejection is respectfully requested.

Rejection of Claims 1, 2, 11 and 12 under 35 U.S.C. § 103(a)

Claims 1, 2, 11 and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 61000017A (hereinafter "Seikagaku"). Applicants respectfully traverse this rejection for at least the following reasons.

Seikagaku discloses a hyaluronic acid composition having a molecular weight of between 4,000 and 2,000,000 daltons with a dosage of 25 mg to 5 g a day by mouth for tissue restoration.

In contrast, the present invention pertains to an orally administered composition in the form of a ***soft gelatin capsule*** that includes hyaluronic acid and its use to improve human skin health. The dosage of the hyaluronic acid in the soft gelatin capsule is between 35 to 45 mg and has a molecular weight between 50,000 and 200,000 daltons.

Seikagaku fails to teach or suggest, provide any motivation or an expectation of success that a skilled artisan would choose to administer hyaluronic acid via a ***soft gelatin capsule*** to improve human skin health. Seikagaku also fails to teach or suggest, provide any motivation or an expectation of success that a skilled artisan would choose to administer 35 to 45 mg of hyaluronic acid in a soft gelatin capsule to improve human skin health. Seikagaku further fails to teach or suggest, provide any motivation or an expectation of success that 35 to 45 mg of hyaluronic acid having a molecular weight of between 50,000 and 200,000 daltons in a soft gelatin capsule would be useful for improving skin health.

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejection of Claims 1-5, 11 and 12 under 35 U.S.C. § 103(a)

Claims 1-5, 11 and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Seikagaku in view of Yano et al. (hereinafter "Yano et al."). Applicants respectfully traverse this rejection for at least the following reasons.

The arguments presented above for Seikagaku are reiterated herein in their entirety.

Yano et al. fail to remedy the deficiencies of Seikagaku. Yano et al. disclose the use of beeswax or rice bran oil as a diluent for α-tocopheryl esters of 5-substituted picolinic acid. α-tocopheryl esters of 5-substituted picolinic acid has no physical or chemical relationship whatsoever to hyaluronic acid. The reference to Yano et al. fails to provide any teaching or suggestion that use of beeswax or rice bran oil could be used for any agent other than α-tocopheryl esters of 5-substituted picolinic acid. Yano et al. fail to provide any basis that would motivate a skilled artisan to use beeswax or rice bran oil as a diluent for anything other than α-tocopheryl esters of 5-substituted picolinic acid. Therefore, Yano et al. also fail to provide an expectation of success that such diluents could be used for any other composition other than α-tocopheryl esters of 5-substituted picolinic acid.

Additionally, the Office Action asserts that Yano et al. teach the use of soft capsules. Yano et al. do not teach or suggest the use of soft ***gelatin*** capsules.

Additionally Yano et al., at column 5, lines 3 through 5 states that "[T]he ***pharmaceutical composition*** of this invention may be in various forms such as soft capsules." (Emphasis added.) Clearly, this is limited to only α-tocopheryl esters of 5-substituted picolinic acids; that being the "pharmaceutical composition" of the Yano et al. reference.

Neither Seikagaku nor Yano et al., alone or in combination, teach or suggest, provide any motivation or an expectation of success that a skilled artisan would choose to administer hyaluronic acid via a ***soft gelatin capsule*** to improve human skin health. Neither Seikagaku nor Yano et al., alone or in combination, teach or suggest, provide any motivation or an expectation of success that a skilled artisan would choose to administer 35 to 45 mg of hyaluronic acid in a soft gelatin capsule to improve human skin health. Neither Seikagaku nor Yano et al., alone or in combination, teach or suggest, provide any motivation or an expectation of success that 35 to 45 mg of hyaluronic acid having a molecular weight of between 50,000 and 200,000 daltons in a soft gelatin capsule would be useful for improving skin health.

It is Applicants position that the Office Action utilizes the combination of references in view of the present invention in a hindsight analysis, which is not permissible by law. In its

simplest form, the Office Action makes the argument that it would be obvious to take ***any compound*** and place it into either beeswax or rice bran oil and/or place the combination in a soft gelatin capsule. The Office Action fails to provide the motivation or an expectation of success why the combination of references would make such a discovery legally obvious. For example, some compounds simply do not solvate well in either beeswax or rice bran oil.

Surely the realization, for example, that a compound could be now combined with either beeswax or rice bran oil, when it may have been known to be solvated in some other diluent, would result in the non-patentability of that combination for ***any*** compound. This is not the correct legal standard. No one knew or appreciated that the compound, in the hypothetical example, could be solvated in either beeswax or rice bran oil, let alone placed into a soft gelatin capsule. This analogy mirrors the present case at hand. The discovery and surprise was that 35 to 45 mg of hyaluronic acid having a molecular weight of between 50,000 and 200,000 daltons could be formulated in a soft gelatin capsule useful for improving skin health. Further, no one knew or appreciated that hyaluronic acid could be formulated with beeswax or rice bran oil. No one had recognized either relationship prior to the presently claimed subject matter; hence the juxtaposition of the impermissible hindsight analysis and/or use of the Applicants' own specification as a blueprint for obviousness.

This becomes an "obvious to try" analysis which is again, not permissible by law. An Applicants' specification and claims cannot be used as a blueprint to solve a previously unknown problem, and then be used against the Applicants.

Reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

This response is being submitted on or before August 11, 2003, making this a timely response (with a two month extension of time). It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief that may be required, or credit any overpayment to Deposit Account No. 04-1420.

Respectfully submitted,

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